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UNITED STATES PATENT APPLICATION

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FOR: SELF-ALIGNING BLOOD COLLECTION TUBE  
WITH ENCODED INFORMATION

BACKGROUND OF THE INVENTION

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1. Field of the Invention

The present invention relates to a blood collection tube having a self-aligning feature and a region for storing optically or magnetically encoded information.

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2. Description of Related Art

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Biological specimens, such as blood, are collected in test tubes and transported to a laboratory for analysis. The laboratory performs the required tests and presents the tests in a report that is sent to the health care provider. Care must be taken to ensure that the test results are properly matched to the patient. As a result, the health care provider labels the test tubes of blood with accurate patient identification information, as well as information to identify health care provider and the tests that need to be performed. The health care provider typically will prepare a plurality of labels that identify both the provider and the patient. The labels may be reviewed with the patient to ensure that relevant material has been properly presented. The health care provider then may apply the labels to the respective test tubes. Information to identify the required tests may be imprinted on the labels or may be indicated by color coding on the tube, or on the tube cap.

5           Laboratories also must take care to ensure that the test results are matched with the proper patient. Most laboratory tests are performed by highly automated machines. However, many laboratories require manual activities to ensure proper cross-referencing of test results to the patient. These manual activities reduce efficiency and create the potential for human error.

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          Some automated machines have a reader for reading indicia. The indicia and the readers can take many forms, including optical readers, such as bar code readers, or magnetically encoded readers for reading digital information encoded on a magnetic stripe. The reader is typically well suited for reading indicia that has been placed on a planar object  
15   that passes in proximity to the reader. Arcuate objects, such as a cylindrical blood collection tube, are not well suited to the automated reading of encoded information. In particular, the arcuate object must be rotated into an orientation where the information is properly aligned with the reader. An improper alignment may cause an improper reading of the information. As a result, systems to read information on a cylindrical or round object may require a  
20   manual task of rotating the cylindrical or round object into a proper orientation to be read by the reader. This need for manual orientation significantly reduces the speed and efficiency of analytical test equipment and creates the potential for human error.

          Accordingly, a need exists for providing alignment capabilities on a cylindrical or  
25   round object to reduce the need for manual orientation of the object in automated machines.

## SUMMARY OF THE INVENTION

          The present invention is a tube for biological fluids, that may be unitarily molded

5 from plastic and includes a closed tapered bottom wall, an open top and a cylindrical sidewall extending therebetween. A cap may be mounted to the open top of the tube for providing a seal across the open top. The tube includes an alignment key to enable a selected rotational orientation of the tube to be attained accurately and automatically. The alignment key preferably is positioned near the tapered bottom wall of the tube to avoid dimensional or  
10 configuration changes to the cylindrical sidewall of the tube. More particularly, the bottom end of the tube may be formed with a projection or indentation that is asymmetrical with respect to the longitudinal axis of the tube. For example, the alignment key may comprise a single fin disposed in a plane that passes through the longitudinal axis of the cylindrical sidewall and that projects outwardly from the tapered bottom wall of the tube. The fin may  
15 have a bottom edge that is orthogonal to the axis of the cylindrical sidewall and substantially tangent to the bottom wall of the tube. The fin may further include a side edge that is parallel to the axis of the tube and substantially collinear with the cylindrical sidewall of the tube.

Alternatively, the tapered bottom end of the tube may be substantially hemispherical,  
20 and the alignment key may define a planar flat formed on the hemispherical bottom wall of the tube. The flat may be aligned to intersect the longitudinal axis of the sidewall at an acute angle.

As a further alternate, the alignment key may comprise an indentation at a selected  
25 rotational position on the tube. For example, the indentation may include a first wall aligned along or parallel to the longitudinal axis of the tube and a second wall aligned at an acute or right angle to the longitudinal axis of the tube. The first and second walls of the indentation may intersect one another at a selected angle, such as a right angle.

5           The tube further includes a region for encoded information, such as optically or magnetically encoded information. The region for encoded information is provided at a selected rotational position on the tube relative to the alignment key. For example, the region for encoded information may be on a portion of the cylindrical sidewall of the tube that is diametrically opposite the alignment key. Alternatively, the area for encoded information  
10   may be at a predetermined angular offset about the longitudinal axis relative to the alignment key.

          The tube may further include a label for applying specified encoded information. The label may be applied at the place of manufacture of the tube to ensure accurate positioning  
15   relative to the alignment key. The label may be adhesively applied and may be coated with a selected material to inhibit separation from the tube and to provide a smooth outer surface that avoids interference with packaging material or with laboratory equipment. The information encoded on the tube may merely be alphanumeric information to define a specific unique code. The code that is provided on the tube then may be correlated to a  
20   specific patient by the health care provider, to effectively become an identification number for that patient. Alternatively, the encoded information on the tube may be provided with a writable portion that will enable information to be added to the encoded region of the tube by the health care facility. Thus, for example, a magnetic strip on the tube may be encoded with information that identifies the specific patient, the health care provider for which the  
25   tests are being performed and/or the types of tests to be carried out at the laboratory.

          The tube may be filled with blood or other biological fluid to be tested in the conventional manner. The tube then is transported to the laboratory for analysis. The tube is positioned in the laboratory equipment such that the alignment key engages an alignment

5 structure on the laboratory equipment. Thus, complete nesting of the alignment key on the tube with the key or key way on the laboratory equipment ensures that the encoded information is properly positioned to be read efficiently and accurately by automated reading equipment on the laboratory apparatus whereby the information is read on the tube from a specified angular position relative to the alignment key. As a result, test reports can be  
10 automatically and accurately matched with the patient information on the tube and subsequently can be transmitted to the appropriate health care provider. An alignment of the tube that could lead to a misreading of indicia is substantially prevented by the proper mating of the alignment key with the key or keyway on the apparatus and by the preselected orientation of the alignment key with the encoded information on the tube.

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#### DESCRIPTION OF THE DRAWINGS

FIG. 1 is a side elevational view of the tube of the present invention.

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FIG. 2 is a rear elevational view of the tube shown in FIG. 1.

FIG. 3 is a bottom plan view of the tube shown in FIGS. 1 and 2.

FIG. 4 is a side elevational view, partly in section, of an alternate embodiment of the  
25 tube of the present invention.

FIG. 5 is a rear elevational view of the tube shown in FIG. 4.

FIG. 6 is a side elevational view of an alternate embodiment of the tube of the present

5 invention.

FIG. 7 is a rear elevational view of the tube shown in FIG. 6.

#### DETAILED DESCRIPTION

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Referring to the drawings in which like reference characters refer to like parts throughout the several views thereof, FIGS. 1-3 illustrate a tube **10** with an alignment key **20**. Tube **10** is unitarily molded from a thermoplastic material and includes a closed bottom **12**, an open top **14** and a cylindrical sidewall **16** extending therebetween. A closure **18** is  
15 sealingly engaged with portions of sidewall **16** adjacent open top **14**, such that a vacuum is defined within tube **10**.

Closed bottom end **12** of tube **10** is substantially hemispherical, and hence conforms with the conventional shape required by many types of automated laboratory equipment that  
20 would be used to perform tests on blood or other biological samples in tube **10**. However, bottom end **12** of tube **10** is provided with an alignment key **20**.

Alignment key **20** is a substantially planar fin that lies in a plane passing through the longitudinal axis of cylindrical sidewall **16**. Alignment key **20** includes a bottom edge **22**  
25 that is aligned substantially orthogonal to the longitudinal axis of cylindrical sidewall **16** and substantially tangent to the hemispherical bottom of tube **10**. The fin of alignment key **20** further includes a side edge **24** aligned substantially parallel to the longitudinal axis of cylindrical sidewall **16** and substantially collinear with a portion of cylindrical sidewall **16**. Thus, bottom edge **22** and side edge **24** of alignment key **20** are substantially orthogonal to

5 one another.

Tube 10 further includes an array of readable information 26 on a selected portion of sidewall 16 that is at a specified rotational orientation with respect to alignment key 20. As shown in FIG. 1, array 26 of information extends longitudinally along cylindrical sidewall 16 at a location spaced 90° from alignment key 20. Array 26 of information may be a magnetic stripe printed directly on the plastic material of tube 10.

Alternatively, array 26 of information may be provided initially on a label which then is adhered to cylindrical sidewall 16. Information presented on the label may be magnetically encoded information or optically encoded information. For example, optically encoded information may include a bar code that is readable by an optical scanner. The bar code may be of any type such as a linear bar code or a two dimensional dot matrix maxicode. The label may further include color-coded indicia, such as a color stripe. Color coded indicia on a label can avoid the need to employ a plurality of color-coded caps or closures, thereby simplifying inventory requirements.

Tube 10 can be used to collect a sample of a biological fluid such as blood for analysis. Tube 10 then is transported to a laboratory for analysis.

The laboratory equipment has a keyway dimensioned and disposed to receive alignment key 20. Engagement of alignment key 20 in the correspondingly configured key way of the laboratory equipment will ensure proper positioning and alignment of array 26 of information to be read by a magnetic reader or optical reader associated with the laboratory equipment for reading information on tube 10. The information read from array

5     **26** will positively identify the patient from whom the blood sample was collected, the health care facility to which test results are to be directed and types of test to be carried out.

          An alternate embodiment of the present invention is illustrated in FIGS. 4 and 5. Tube **110** is unitarily molded from a thermoplastic material and includes a hemispherical  
10     bottom wall **112**, an open top **114** and a cylindrical sidewall **116** extending therebetween. An alignment key **120** extends inwardly on hemispherical bottom wall **112**. More particularly, alignment key **120** effectively defines a notch having a horizontally aligned base wall **122** extending substantially orthogonally to the longitudinal axis of cylindrical sidewall **116**. The notch of alignment key **120** further includes a vertically aligned base wall  
15     extending substantially along the longitudinal axis of the cylindrical sidewall **116**. Alignment key **120** further includes a pair of side walls **123** which are aligned parallel to the longitudinal axis of cylindrical side wall **116** and perpendicular to base walls **122** and **124** respectively.

20           Cylindrical sidewall **116** of tube **110** includes an array of information **130** at a selected rotational position relative to alignment key **120**. As shown in FIGS. 4 and 5, array of information **130** is 90° offset from alignment key **120**.

          In use, a biological fluid sample such as blood is collected in tube **110** and transported  
25     to a laboratory. Laboratory equipment is provided with a projection dimensioned and disposed to mate with alignment key **120**. A nesting of the projection on the laboratory equipment with key **120** will ensure that array **130** of information aligns with a reader provided on the laboratory equipment. Array **130** of information may be disposed on sidewall **116** as described above with respect to test tube **10**.



5           An alternate embodiment of the present invention is illustrated in FIGS. 6 and 7. Tube **210** includes a generally hemispherical bottom wall **212**, an open top **214** and a cylindrical sidewall **216** extending therebetween. An alignment key **220** is formed on bottom wall **212** and defines a flat surface aligned at an acute angle to the axis of cylindrical sidewall **216**. An array **230** of information is disposed along cylindrical sidewall **216** at a specified  
10   angular position relative to alignment key **220**. In particular, as shown in FIGS. 6 and 7, alignment key **220** is offset from array **230** of information by 90°. Array **230** of information may take any of the forms described above with respect to tube **10**. Additionally, tube **210** is used in precisely the manner of tubes **10** and **110** described above.

15           While the invention has been described with respect to several embodiments, it is apparent that various changes can be made without departing from the scope of the invention as defined by the appended claims. In particular, alignment keys of other shapes may be employed. Additionally, other machine-readable information may be provided on the tube at a specified rotational position relative to the alignment key. Additionally, the rotational  
20   position of the array of information and the alignment key can differ from the 90° offset illustrated in the figures. For example, a 180° offset or perfect alignment of (i.e., 0° offset) may be provided in accordance with the configuration of the laboratory equipment.